EXHIBIT “A”

IN THE CIRCUIT COURT
FOR THE CITY OF ROANOKE

MARY SHARON WALKER

Plaintiff,

v.

CASE NO.: CL12-2077

DIVISION:

NEW ENGLAND COMPOUNDING PHARMACY, INC., D/B/A NEW ENGLAND COMPOUNDING CENTER,

Serve: Secretary of the Commonwealth
4th floor
Patrick Henry Building
1111 East Broad Street
Richmond, VA

IMAGE GUIDED PAIN MANAGEMENT, P.C., D/B/A INSIGHT IMAGING ROANOKE
2923 Franklin Road Southwest
Roanoke VA 24014

Serve R/A: Herman Marshall III
10 S. Jefferson St. Suite 1400
Roanoke VA 24011

Defendants.

COMPLAINT

Plaintiff, Mary Sharon Walker, by and through her undersigned counsel, brings this Complaint and respectfully moves this court for judgment against the Defendants, individually, jointly and severally, for the following reasons:

1. Mary Sharon Walker (Plaintiff) is a resident of Roanoke, Virginia. At all relevant times, Plaintiff has been a resident and citizen of Virginia.

DEFENDANT'S EXHIBIT A tabbies

Filed in the Clerk's Office this 23rd day of Oct 20 12

Writ Tax	$ 25.00	208 Fee	$
Fee	$ 50.00	Tests:	229-30.00
Ub Fee	$ 4.00	BRENDA S. HAMILTON, CLERK	
123 Fee	$ 4.00		
106 Fee	$ 5.00		
170 Fee	$ 10.00		
147 Fee	$ 4.00		
Total Paid	$ 346.00		

2. New England Compounding Pharmacy, Inc., D/B/A New England Compounding cnter (NECC) is a Massachusetts corporation that maintains its principal place of business at 697 Waverly Street in Framingham, Massachusetts.

3. NECC is in the business of manufacturing, marketing, and selling medicines. Among the products that NECC manufacturers, markets, and sells is methylprednisolone acetate, an injectable steroid.

4. Image Guided Pain Management, P.C. is a Virginia Corporation with its principal place of business at 2923 Franklin Road SW, Roanoke, Virginia. Image Guided Pain Management, P.C. is in the business of distributing pain management products and devices to its clients.

5. Venue in this forum is proper because Plaintiff resides in Virginia, she received her steroid injection at Insight Imaging in Roanoke, Virginia, received treatment for her injuries at Lewis Gale Hospital in Roanoke, Virginia, and NECC sold and distributed it's product within the city of Roanoke, Virginia. Defendant Image Guided Pain Management, P.C. ("IGPM") has its principal place of business in Roanoke,

6. NECC conducts business, delivers products, and purposefully directs sales and marketing efforts to the city of Roanoke, Virginia and its residents.

7. The steroid, methylprednisolone acetate, was manufactured by NECC. Unknown to Plaintiff, a fungus contaminated the steroid, rendering the material dangerous and unfit for use. NECC produced and sold more than 17,000 single-dose vials of the steroid, which are believed to be contaminated.

8. This case seeks redress for Defendants' sale and injection of the defective and dangerously contaminated steroid, which has caused Plaintiff bodily harm, emotional distress, other personal injuries, and to incur medical and other expenses.

9. NECC voluntarily recalled the steroid, along with scores of other medicines, after the Center for Disease Control and Prevention ("CDC") confirmed an outbreak of fungal meningitis in people who received injections of the steroid.

10. According to the CDC, "[f]ungal meningitis occurs when the protective membranes that cover the brain and spinal cord are infected with a fungus. Fungal meningitis can develop after a fungus spreads through the bloodstream from somewhere else in the body, as a result of the fungus being introduced directly into the central nervous system, or by direct extension from an infected body site next to the central nervous system."

11. As of the filing of this complaint, the CDC was aware of and had confirmed 284 instances in which a person developed fungal meningitis after receiving a steroid injection produced by NECC. The outbreak is present in twenty-three states, including Virginia. At least twenty-three people have died as a result of developing fungal meningitis through an injection of the steroid sold by NECC, according to the CDC.

Factual Background

NECC's production of contaminated steroid

12. NECC is a compounding pharmacy, which means NECC creates custom-mix solutions, creams, and other medications in doses or forms that generally are not commercially available.

13. Compounding pharmacies, such as NECC, are not closely regulated like drug manufacturers, and the products they create are not subject to approval by the Food and Drug Administration ("FDA").

14. NECC manufactured the injectable steroid methylprednisolone acetate at its Massachusetts facility, and it sold tens of thousands of single-dose vials of the substance.

15. In early October 2012, FDA investigators located fungal contamination in a sealed vial of the steroid at NECC's facilities. The discovery prompted NECC to recall the 17,676 single-dose vials of the steroid.

16. Even though NECC recalled the steroid in early October, thousands of people at outpatient clinics and similar facilities in 23 states, including Virginia, were injected with the steroid between July and September 2012.

17. The incubation period for fungal meningitis is anywhere between a few days to several months, so health officials believe the number of victims will increase.

18. According to the CDC, people who develop fungal meningitis may have symptoms that include: headache, fever, nausea, and stiffness of the neck. Infected people may also feel confused, dizzy, or discomfort from bright lights and develop stroke-like symptoms.

19. According to the CDC, at least 2 clinics and facilities in Virginia received and potentially administrated the contaminated steroid, including Insight Imaging in Roanoke, Virginia and New River Valley Surgery Center in Christiansburg, Virginia.

20. Plaintiff received injections of NECC's contaminated steroid on July 27, 2012 and September 20, 2012 at Insight Imaging located in Roanoke, Virginia.

21. After receiving the injections, Plaintiff suffered from severe headaches, dizziness, blurred vision and weakness.

22. Plaintiff then received a telephone call from Insight Imaging informing her that she had received the contaminated steroid sold by NECC and directing her to see a physician to be evaluated for potential fungal meningitis.

23. Plaintiff underwent medical testing including medical blood work, two spinal taps, and other analyses as a result of being injected with NECC's defective and contaminated steroid.

24. Plaintiff was hospitalized as Lewis Gale for 8 days and diagnosed with Fungal Meningitis as a result of receiving the steroid injection manufactured by NECC.

Count I
Design and Manufacturing Defect
Against Defendant NECC

25. Plaintiff re-alleges the foregoing paragraphs, inclusive, as though fully set forth herein.

26. Upon information and belief, NECC is the exclusive designer and manufacturer of the contaminated methylprednisolone acetate steroid doses and is solely responsible for its introduction to the market.

27. The contaminated methylprednisolone acetate steroid doses reached Plaintiff without a substantial change in the condition in which they were manufactured and intended for use.

28. NECC had a duty to use reasonable care in designing and manufacturing the methylprednisolone acetate steroid doses such that they are not unreasonably dangerous to users when used as directed or in a way foreseeable to NECC.

29. NECC breached that duty by designing and manufacturing the methylprednisolone acetate steroid doses in a defective condition unreasonably dangerous to the Plaintiff.

30. The methylprednisolone acetate was defective because: (1) the substance diverged from its intended design and was tainted with fungal matter that harmed Plaintiff; and (2) the design and manufacturing did not satisfy normal consumer expectations.

31. If the methylprednisolone acetate steroid doses had been properly designed and manufactured, Plaintiff would not have been harmed.

32. As a direct and proximate result of NECC's breach of its duty to use reasonable care in the design and manufacture of methylprednisolone acetate, Plaintiff has suffered serious bodily harm, other personal injuries, and emotional distress, and has incurred medical and other expenses.

33. NECC is strictly liable to the Plaintiff for its defective design and manufacture of methylprednisolone acetate.

Count II
Negligence
Against All Defendants

34. Plaintiff realleges the foregoing paragraphs, inclusive, as though fully set forth herein.

35. NECC was negligent because it failed to use reasonable care when it designed, tested, manufactured, marketed, and sold doses of methylprednisolone acetate.

36. As the designer, tester, manufacturer, and / or seller of consumer products, NECC owed a duty to Plaintiff to provide a safe and quality product. NECC breached those duties.

37. NECC negligently allowed its steroid product to become contaminated with fungus during the compounding, manufacturing, packaging and distribution of the product and negligently operated a compounding laboratory using non-sterile practices and procedures.

38. Upon information and belief, New England Compounding Center manufactured large batches of steroid without proper prescriptions in violation of federal and state regulations and other industry standards.

39. According to the FDA publication, NECC had been cited previously for failure to use proper sterilization practices.

40. Despite NECC's history of improper practices, Insight Imaging negligently purchased steroids from NECC when it knew or should of known that its products were not reasonably safe to administer to patients.

41. Insight Imaging negligently and carelessly selected a compounding pharmacy to purchase their medicines from who they knew or should have known did not follow proper practices and procedures for the safe manufacturer of products it purchased which it then administered to the plaintiff.

42. As a direct and proximate result of Defendants' negligence, lack of care, and other wrongful acts, Plaintiff sustained and will sustain damages.

43. As a result of Defendants' negligence, Plaintiff has suffered serious bodily harm, other personal injuries, and other emotional distress, and has incurred medical and other expenses as a direct cause of being injected with contaminated doses of methylprednisolone acetate.

44. As a direct, proximate and foreseeable result of Defendants' negligence, Plaintiff has been damaged in an amount to be determined at trial.

Count III
Breach of Express Warranty
Against All Defendants

45. Plaintiff realleges the foregoing paragraphs, inclusive, as though fully set forth herein.

46. Defendants designed, manufactured, tested, marketed and distributed into the stream of commerce the methylprednisolone acetate.

47. Defendants expressly warranted that the methylprednisolone acetate was safe and effective.

48. The methylprednisolone acetate placed into the stream of commerce by NECC and IGPM did not conform to these express representations because it was contaminated with fungus.

49. Defendants breached their express warranties under Virginia Code Section 8.2-313.

50. As a direct and proximate result of Defendants' breach of express warranties regarding the safety and effectiveness of the methylprednisolone acetate, Plaintiff has suffered significant damages, including but not limited to physical injury, economic loss, pain and suffering, and will continue to suffer such damages in the future.

Count IV
Breach of Implied Warranties
Against All Defendants

51. Plaintiff incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further alleges as follows:

52. Defendants designed, manufactured, tested, marketed and distributed into the stream of commerce the methylprednisolone acetate.

53. At the time Defendants designed, manufactured, tested, marketed and distributed into the stream of commerce the methylprednisolone acetate, Defendants knew the use for which the methylprednisolone acetate was intended, and impliedly warranted the methylprednisolone acetate to be of merchantable quality and safe for such use.

54. Plaintiff reasonably relied upon the skill and judgment of Defendants as to whether the methylprednisolone acetate was of merchantable quality and safe for its intended use.

55. Defendants breached their implied warranty of merchanability under Virginia Code Section 8.2-314.

56. Contrary to Defendants' implied warranties, the methylprednisolone acetate was not of merchantable quality or safe for its intended use, because the methylprednisolone acetate was unreasonably dangerous as described above.

57. As a direct and proximate result of Defendants' breach of implied warranties regarding the safety and effectiveness of the methylprednisolone acetate, Plaintiff has suffered significant damages, including but not limited to physical injury, economic loss, pain and suffering, and will continue to suffer such damages in the future.

58. As a result of the aforesaid negligence, breach of warranties, and any statutory or regulatory violations of Defendants, Plaintiff was seriously and permanently injured. He has suffered physical pain, discomfort and mental anguish, and these will or may continue in the future; he has incurred substantial expenses for treatment by physicians and related medical care, and in the future he will or may likely continue to incur such expenses in an effort to be cured and healed; he has been unable to perform many of the usual personal affairs of a man of his age and position in life and, in the future, he will or may continue to be unable to perform such affairs.

WHEREFORE, for the reasons stated above, Plaintiff, Mary Sharon Walker, respectfully requests that he be awarded a judgment, individually, jointly and severally, against New England Compounding Pharmacy, Inc., D/B/A New England Compounding Center and Image Guided Pain Management, P.C. d/b/a Insight Imaging Roanoke in the amount of Five Million Dollars ($5,000,000.00), together with post-judgment interest and costs of this proceeding, as well as such other and further relief as may be appropriate under the circumstances of this case.

A TRIAL BY JURY IS HEREBY DEMANDED.

Dated: 10/22/12

THE MOODY LAW FIRM, INC.

By: _____

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(540) 540/672-3055

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October 22, 2012

CIRCUIT COURT
Received & Filed
2:56pm
OCT 23 2012
By [signature] Deputy Clerk
CITY OF ROANOKE

VIA FEDERAL EXPRESS

Brenda S. Hamilton, Clerk
Roanoke City Circuit Court
315 West Church Avenue, 3rd Floor
Roanoke, VA 24010-2610

Re: Mary Sharon Walker v. New England Compounding Pharmacy Inc., et al
Circuit Court for the City of Roanoke CL12-2077

Dear Ms. Hamilton:

Enclosed please find an original and 3 copies of a Complaint I have prepared in connection with the above referenced matter for filing with the court. Additionally, please find our firm's check in the amount of $346.00 payable to your order for the fees. The Complaint for the below listed defendants will be served by a private process server at a later date. Please prepare the Complaint for service on the Defendants whose addresses are:

Secretary of the Commonwealth
4th Floor
Patrick Henry Building
1111 East Broad Street
Richmond, VA

Herman Marshall III
10 S. Jefferson Street, Suite 1400
Roanoke, VA 24011

Kindly return the Complaints in the enclosed, self-addressed stamped envelope.

Thank you for your assistance in this matter.

Very truly yours,

THE MILLER FIRM, LLC

Richard Mayer
Paralegal to Michael J. Miller

:rmm
Enclosure
cc: Willard J. Moody, Jr., Esquire